PATENT
Customer No. 22,852
Attorney Docket No. 09960.0001-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Campbell et al.	)	Group Art Unit: 1632
	)	
Application No.: 09/658,862	)	Examiner: Deborah Crouch
	)	
Filed: September 8, 2000	)	Confirmation No.: 2555
	)	
For: UNACTIVATED OOCYTES AS CYTOPLAST RECIPIENTS FOR NUCLEAR TRANSFER	)	

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

In response to the Examiner's Answer dated September 12, 2006, Appellants submit the following remarks. This Reply Brief is due November 12, 2006, and is timely filed.

1. The Examiner has not applied the correct legal standard for statutory double patenting

In the Examiner's Answer, the Examiner bases the statutory double patenting rejection on an alleged inability to identify the donor mammal after the clone has been produced. (Examiner's Answer at 15.) The Examiner's analysis is legally flawed. The legal issue here can be resolved by the test set forth in *In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970)(cited as a "reliable test" in M.P.E.P. § 804 (II)(A)), which is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention, and there is no double patenting. *Id.* Since the Examiner does not use this test, she reaches the wrong conclusion. When applied to the claims in this application, this test shows that no statutory double patenting exists.

The claims in the present application require that the parental donor mammal is "non-embryonic." Thus, the parental donor animal **can** be foetal, and clone of this foetal mammal would be encompassed by the claims of the present application. In contrast, the claims in Application No. 09/658,862 ("the '862 application") require that the parental donor mammal is "non-embryonic, non-foetal." Thus, the parental donor animal **cannot** be foetal. A clone of a foetal mammal, although encompassed by the claims of the present application, would not infringe the claims in the '862 application, in which the parental donor mammal **cannot** be foetal. According to the test set forth in *Vogel*, this result precludes statutory double patenting under 35 U.S.C. § 101.

2. The Examiner has not applied the correct legal standard for determining non-statutory subject matter

In the Examiner's Answer, the Examiner admits that nuclear transfer methods have the "hand of man." (Examiner's Answer at 18.) Nonetheless, the Examiner questions whether the product of nuclear transfer has the "hand of man." (*Id.*) The Examiner's question arises from an

alleged inability to distinguish Appellants' clone from the same animal produced sexually. (*Id.*) The Examiner is not applying the correct test for patentable subject matter under 35 U.S.C. § 101.

The Supreme Court has found that section 101 is extremely broad and encompasses human-made inventions, as opposed to products of nature:

> As this Court recognized over 20 years ago in *Chakrabarty*, 447 U. S., at 308, the language of §101 is extremely broad. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Ibid.* This Court thus concluded in *Chakrabarty* that living things were patentable under §101, and held that a manmade micro-organism fell within the scope of the statute. As Congress recognized, "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *Id.*, at 313.

E.M. Ag Supply Inc. v. Pioneer Hi-Bred International Inc., 60 U.S.P.Q.2d 1865, 1868 (2001). Appellants' claims expressly recite a "clone," which is an asexually produced animal that does not occur in nature. It is indisputable that Appellants' clone is a human-made invention. Thus, Appellants' clone is patentable subject matter.

3. The Examiner has not applied the correct legal standard for determining enablement

In the Examiner's Answer, the Examiner does not use the correct test for enablement. The test of enablement is whether one of skill in the art could make and use ***the claimed invention*** from the disclosures in the specification coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988).

Success does not negate enablement

The Examiner's basis for questioning the enablement of Appellants' invention is that the subsequent successful cloning of mice, rabbits, horses, and rats used "method steps not taught by

the present specification." (Examiner's Answer at 7.) This basis is insufficient. The issue is not how others cloned mice, rabbits, horses, and rats, but whether Appellants' claimed invention is enabled. The fact that others may have used a somewhat different procedure to clone the animals does not negate the enablement of Appellants' claimed invention.

The Examiner's comparison of what specific steps were used by others for cloning to the steps of Appellants' claimed invention is incomplete. The success of others in cloning mice, rabbits, horses, and rats does not mean that the steps that they used are absolutely necessary to clone these mammals. Rather, it simply means that the particular steps used by those practitioners provided a sufficient efficiency to achieve cloned animals. It also shows that each of those species can be successfully cloned by methods quite similar to those disclosed in Appellants' specification.

Inefficiency does not negate enablement

There is no evidence of record that Appellants' claimed invention will not work without any undue experimentation if it is repeated a sufficient number of times. Repeating the same procedure additional times cannot be considered undue experimentation. Rather, since any experimentation would be repetitive, it would be routine, and routine experimentation does not negate enablement. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The Examiner's equating of inefficiency with undue experimentation (Examiner's Answer at 20) is unsupported by the evidence of record.

Moreover, the burden of showing non-enablement is on the Office. *See In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1410, 1413 (Fed. Cir. 1993). The burden is not on Appellants to show enablement. Consequently, the burden is on the Office to show that Appellants' procedure would not work if repeated a sufficient number of times, not on Appellants to show that it would work. The Examiner's attempt to shift the burden to Appellants is in error. (Examiner's Answer

at 22: "Appellant's argument, if enough reconstructed embryos are made, eventually, a cloned mammal using the presently claimed method will result, is not supported by evidence.")

Furthermore, as made clear in *Telectronics*, Appellants' disclosure must be considered together with the information known in the art. *See* 857 F.2d at 785, 8 U.S.P.Q.2d at 1223. The Examiner does not discuss why the differences that do exist between Appellants' claims and the protocols cited by the Examiner to successfully clone mice, rabbits, rats, and horses, could not have been provided by information known in the art. Instead, the Examiner focuses on the whether the specification specifically provides this information. This is legally incorrect. The Examiner must consider whether the information known in the art could be combined with Appellants' disclosure to achieve Appellants' claimed invention. *See id.* When analyzed under the correct legal standard, Appellants' claims fulfill the enablement requirement of 35 U.S.C. § 112, first paragraph.

4. The Examiner has not applied the correct legal standard for anticipation

On pages 31 of the Examiner's Answer, the Examiner argues that, regardless of phenotypic differences, a clone would not be novel over the nuclear donor mammals because it would not have any "patentably distinguishing characteristics." The Examiner's position is legally incorrect. The test for anticipation is whether the prior art discloses the ***identical invention*** as Appellants' clone. *See Richardson v. Suzuki Motor Co. Ltd.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Anticipation is not shown by a ***non-identical*** prior art disclosure, even it if is "substantially the same" as the claimed invention. *Jamesbury Corp. v. Litton Indust. Prod., Inc.*, 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). Any difference between the clone and the parent precludes anticipation because the parent and the clone are non-identical. Appellants have provided extensive objective evidence that a clone and its parental donor mammal are always

different due the effects of different oocytes and environmental factors. Thus, Appellants' claimed clone cannot be anticipated by its parental donor mammal.

On page 34 of the Examiner's Answer, the Examiner contends that age cannot be a determining factor in patentability of a clone over pre-existing mammals and that novelty of the clone over the parental donor mammal cannot be based on age. The Examiner's position is not supported by any legal citation. Age is a characteristic of every mammal, and any difference is relevant for purposes of determining anticipation. If two mammals are of different ages, they cannot be identical.

Moreover, Appellants' claims intrinsically require two mammals to have existed, the clone and its parent, which have different time periods during which they are alive and a special relationship between their genetic complement. This intrinsic limitation of Appellants' claims cannot be anticipated by a single mammal. Since these two mammals have the same genetic complement, they also cannot be anticipated by two mammals that do not have this limitation, such as a parental cow and her sexually produced calf.

5. The Examiner has not applied the correct legal standard for obviousness

On pages 35-36 of the Examiner's Answer, the Examiner alleges that because Appellants' clone and its parent have the same set of chromosomes, they are obvious over each other. The Examiner further contends that "Dolly the sheep is indeed obvious over her mother." (*Id.*) The Examiner conclusions are legally incorrect. The Examiner's conclusions ignore the fact that Dolly's nuclear donor mammal (*i.e.*, mother) was a six years old sheep. Appellants' claims require a difference in age between the donor and the clone and require that the donor and the clone have the same genetic complement. These two features together preclude a finding of obviousness of Appellants' clone. The correct analysis for obviousness must consider these two

elements of Appellants' claimed clones together. *See Grain Processing Corp. v. Am. Maize Prods.*, 840 F.2d 902, 907-08, 5 U.S.P.Q.2d 1788 (Fed. Cir. 1988). When these two elements of Appellants' claimed clone are considered together, Appellants' clone cannot be considered obvious.

Moreover, Appellants claims intrinsically require two mammals to have existed, the clone and its parental donor mammal, which have different time periods during which they are alive and a special relationship between their genetic complement. This intrinsic limitation of Appellants' claims cannot be obvious over a single mammal. Since these two mammals have the same genetic complement, they also cannot be obvious over two mammals that do not have this limitation, such as a parental cow and her sexually produced calf.

Appellants request that each ground for rejection be reversed.

Please grant any extensions of time required to enter this Reply Brief and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: November 13, 2006

By: _____

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